conform to the anatomic contour of at least a portion of a second lateral aspect of the vertebral bodies opposite the first lateral aspect.

140. The implant of claim 102, further in combination with hydroxyapatite.--

REMARKS

Applicant cancelled claim 35, amended claims 1 and 34, and added new claims 102-140 to further define Applicant's claimed invention. The amendment to claim 1 is supported by the language of claims 34 and 35 as originally filed, and page 13, lines 1-7 of the specification. New independent claim 102 is supported by claims 1 and 3 as originally filed. New claims 103-139 are supported by claims 6-42, respectively, as originally filed. New claim 140 is supported by page 6, line 3 of the specification.

Claims 102, 103, 105-107, 111, 112, 115-132, 135, and 137-140 read on Group 1, Species 1 as defined by the Restriction Requirement of November 30, 2001. Applicant consents to the withdrawal of claims 108-110 and 113 as being directed to non-elected Species 2. Applicant submits that independent claim 102 is a linking claim to at least species I and II. MPEP § 809.04 states that "[i]f a linking claim is allowed, the examiner must thereafter examine species if the linking claim is generic thereto, or he or she must examine the claims to the non-elected inventions that are linked to the elected invention by such allowed linking claim." (MPEP page 800-52, col. 2 (August 2001)). Accordingly, Applicant submits that upon allowance of linking claim 102, at least the non-elected dependent claims 108-110 and 113 drawn to species II must be rejoined and examined under 37 C.F.R. § 1.104 for patentability.

For claims 104, 114, 133, 134, and 136, Applicant submits that certain of the

claimed features described in the specification and not illustrated do not require a drawing since the subject matter would be understandable to one of ordinary skill in the art. 35 U.S.C. § 113, first sentence, states that "the applicant shall furnish a drawing where necessary for the understanding of the subject matter to be patented." For example, claim 136 recites opposed portions that are in moveable relationship to each other which would be understandable to one of ordinary skill in the art.

The Examiner did not consider the references listed in the Information Disclosure Statement dated September 18, 2001 and selected references listed in the Information Disclosure Statement dated April 14, 2000. Applicant is submitting with this response a supplemental IDS with the references not previously considered by the Examiner with corresponding English language abstracts, English translations, or U.S. equivalent patents, respectively. (See, MPEP § 609(III)(A)(3), 2nd col., page 600-122 (August 2001)).

In the Office Action dated May 15, 2002, the Examiner withdrew dependent claim 101 directed to the combination of an implant with hydroxyapatite. Applicant respectfully traverses the Examiner's designation of claims being withdrawn. In the Reply dated April 30, 2002, Applicant elected claims 1, 3, 5, 6, 8-10, 14, 15, 18-35, 38, and 40-42, and cancelled claims 43-100. Therefore, the correct designation of claims being withdrawn is 2, 4, 7, 11-13, 16, 17, 36, 37, and 39. The subject matter of claim 101 is readable on all species. Applicant therefore respectfully requests the rejoinder and examination of claim 101.

The Examiner rejected claims 1, 3, 5, 6, 8-10, 14, 15, 18-35, 38, and 40-42 as being unpatentable under the judicially created doctrine of obvious-type double

patenting over claims 1-77 of U.S. Patent No. 6,241,770. Applicant respectfully traverses the rejection. Applicant notes that the Examiner failed to identify the differences between the inventions defined by the conflicting claims (the claims in the patent versus the claims of the application) and state reasons why a person of ordinary skill in the art would conclude that the inventions defined in the claims at issue are an obvious variation of the invention defined in the claims of the patent as required by the MPEP. (See, MPEP § 804(II)(B)(1), page 800-22, 2nd col. (August 2001)).

In the Restriction Requirement of November 30, 2001, the Examiner required election between Species 1 showing an implant having non-arcuate opposed portions in Fig. 5, and Species 2 showing an implant having arcuate opposed portions in Fig. 10. Applicant elected claims readable on the generally non-arcuate implant of Fig. 5. All of the claims of the '770 patent are directed to arcuate implants. Thus, Applicant submits that claims 1, 3, 5, 6, 8-10, 14, 15, 18-35, 38, and 40-42 are patentably distinct from claims 1-77 of the '770 patent at least due to the distinction made by the Examiner between non-arcuate and arcuate implants in the restriction requirement.

The Examiner also rejected claims 1, 3, 5, 6, 8-10, 14, 15, 18-35, 38, and 40-42 as being unpatentable under the judicially created doctrine of obvious-type double patenting over claims 1-74 of U.S. Patent No. 6,350,283. Applicant respectfully traverses the rejection. Claims 1-36 of the '283 patent are directed to an implant formed of bone and having at least one through hole having a maximum cross-sectional dimension greater than 0.5 mm. The claims of the present application are directed to an artificial implant formed of a material other than bone comprising at least one of surgical quality titanium and its alloys, cobalt chrome alloy, tantalum, any metal

or alloy suitable for the intended purpose, any ceramic material suitable for the intended purpose, and any plastic or composite material suitable for the intended purpose. The specification of the '283 patent specifically excludes "materials other than bone for use as the base material used to form the implant." (See, '283 patent, col. 6, lines 49-50). Applicant submits that claims 1, 3, 5, 6, 8-10, 14, 15, 18-35, 38, and 40-42 are patentably distinct from claims 1-36 of the '283 patent at least due to the distinction between the material composition of the implants of the separate inventions.

Claims 37-73 of the '283 patent are directed to an implant formed of bone having opposed arcuate portions. The claims of the present invention are directed to artificial implant having opposed portions being non-arcuate along at least a portion of the length of the implant, the implant being formed of a material comprising at least one of surgical quality titanium and its alloys, cobalt chrome alloy, tantalum, any metal or alloy suitable for the intended purpose, any ceramic material suitable for the intended purpose, and any plastic or composite material suitable for the intended purpose. Applicant submits that claims 1, 3, 5, 6, 8-10, 14, 15, 18-35, 38, and 40-42 are patentably distinct from claims 37-73 of the '770 patent at least due to the distinction between the material composition of the implants of the separate inventions and the distinction between non-arcuate and arcuate implants in the restriction requirement.

Claim 74 of the '283 patent is directed to a method of installing an implant formed of bone and having at least one through-hole having a maximum cross-sectional dimension greater than 0.5 mm. The claims of the present application are directed to an artificial implant, the method of the present invention having been restricted out by the Examiner in the restriction requirement. Accordingly, applicant

submits that claims 1, 3, 5, 6, 8-10, 14, 15, 18-35, 38, and 40-42 are patentably distinct from claim 74 of the '283 patent.

The Examiner rejected claims 8, 9, 14, and 35 under 35 U.S.C. § 112, second paragraph, as being indefinite. In response to the Examiner's request for an explanation, in claim 8 the subject matter is drawn to an implant where less than half of the leading end is linear along a plane perpendicular to the mid-longitudinal axis. As to claim 9, the subject matter is drawn to an implant where more than half the leading end is a curve extending from the exterior side toward the mid-longitudinal axis. Reference to a plane "dividing said implant into an upper half and a lower half" in claims 8 and 9 is to emphasize that the leading end is curved from the exterior side toward the mid-longitudinal axis at least proximate the center of the height of the leading end.

As to claim 14, Applicant submits that the use of the term "porous" relative to the opposed portions is clear. Merriam Webster's Dictionary defines "porous" as "capable of being penetrated." (See, Merriam Webster's Collegiate Dictionary, 10th Ed., page 907 (1999), a copy of which is attached hereto). The Examiner is correct in that elements 110 shown in Fig. 5 illustrate one example of an opposed portion that is porous, although other configurations are possible as would be understood by one of ordinary skill in the art.

As to the limitation previously recited in cancelled claim 35 and now in claim 1, Applicant submits that the phrase "hollow interior" is clear and supported by the specification. In reference to Fig. 5, the specification states that:

> [o]pposed portions 106, 108 are spaced apart and connected by an interior side wall 112 and an exterior side wall 114 opposite interior side wall 112. Interior side wall 112 is the portion of implant 100 adapted to be placed toward another implant when implant 100 is inserted in pairs into

the disc space between the adjacent vertebral bodies to be fused. Interior side wall 112 is not the internal surface of a hollow interior of implant 100. Exterior side wall 114 is adapted to be placed into the disc space nearer to the perimeter of the vertebral bodies than interior side wall 112. Side walls 112, 114 may also include at least one opening for permitting for the growth of bone therethrough.

(Specification, page 16, lines 15-23). The spaced apart opposed portions and sidewalls of the implant define a hollow interior. The specification further states that "[i]mplant 100 may further be hollow or at least in part hollow." (See, Specification, page 17, lines 3-4).

The Examiner rejected claims 1, 3, 5, 6, 8-10, 14, 15, 23, 24, 33-35, 38, and 40-42 under 35 U.S.C. § 102(b) as being anticipated by French Publication No. 2,703,580 to Gilles. Applicant amended independent claim 1 to recite an implant with "opposed portions having at least one opening therein to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant " where each of the opposed portions have "a vertebral body contacting surface between said at least one opening and at least one of said interior side wall and said exterior side wall, each of said vertebral body contacting surfaces being adapted to be placed toward one of the adjacent vertebral bodies, said vertebral body contacting surfaces being spaced apart to define a hollow interior in communication with said openings." Further, the implant of claim 1 has a width that is less than approximately one-half of the maximum width of the adjacent vertebral bodies into which the implant is adapted to be inserted.

Gilles teaches an intersomatic cage adapted for placement in the cervical spine having two "seatings" 3 and 4 into which bone grafts are inserted. (See, English translation of Gilles, page 4, lines 15-22, a copy of which is submitted in the Information Disclosure Statement being filed concurrently herewith). The implant of Gilles is a

single, one-piece construction. (See, e.g., English translation of Gilles, page 5, lines 7-9 which discuss the vertical radiopaque mark shown in Fig. 1). Fig. 1 and page 3, lines 4-17 of the English translation of Gilles show and describe an implant that is centrally placed between the adjacent vertebral bodies. If the Gilles implant were to have a width less than one-half of the maximum width of the adjacent vertebral bodies into which it is inserted, the centrally placed implant would not support the adjacent vertebral bodies in a stable relationship to one another. The implant would act as a fulcrum so that the vertebral body would rock over the implant much like a board over a barrel. Thus, Applicant submits that Gilles does not teach or suggest an implant having a width less than approximately one-half the maximum width of the adjacent vertebral bodies into which the implant is adapted to be inserted as claimed in independent claim 1. Gilles also does not teach or suggest an implant with opposed portions having at least one opening therein and having a vertebral body contacting surface spaced apart to define a hollow interior in communication with the openings. Thus, Applicant submits independent claim 1 is allowable and that dependent claims 3, 5, 6, 8-10, 14, 15, 23, 24, 33-35, 38, 40-42, and 101 are allowable at least because they depend directly or indirectly from an allowable independent claim.

The Examiner also rejected claims 1, 3, 5, 6, 8-10, 14, 15, 23, 24, 33-35, 38, and 40-42 under 35 U.S.C. § 102(b) as being anticipated by French Publication No. 2,724,312 to Albert. Albert teaches an intersomatic spacer with an open plan to allow "osseous filling" with bone mass. (See, English translation of Albert, numbered page 4, lines 8 and 9, a copy of which is submitted in the Information Disclosure Statement being filed concurrently herewith). In order to retain the bone mass between the walls,

Albert teaches the use of wire threads 39 or "internal back drafts." (See, English translation of Albert, numbered page 6, lines 6-11 and Fig. 5, which shows a perspective view of the wire threads 39 attached to openings 38). Albert does not teach or suggest an implant with opposed portions having at least one opening therein and having a vertebral body contacting surface, spaced apart to define a hollow interior in communication with the openings. Albert teaches away from the present invention by discussing the disadvantage such implants have with MRIs, such as creating artifacts in the MRI image. (Albert, English translation, page 1, lines 12-13). Applicant submits independent claim 1 is allowable and that dependent claims 3, 5, 6, 8-10, 14, 15, 23, 24, 33-35, 38, 40-42, and 101 are allowable at least because they depend directly or indirectly from an allowable independent claim, which is submitted to be allowable over the cited reference.

The Examiner also rejected claims 18-22 and 25-32 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,609,635 to Michelson. Applicant submits that the rejection over claims 18-22 and 25-32 is rendered moot at least in view of the patentability of independent claim 1, which Applicant submits is in condition for allowance and from which the rejected dependent claims depend either directly or indirectly.

Newly added independent claim 102 recites an implant having a third distance as measured from the junction of the leading end and the interior side wall to the plane perpendicular to and bisecting the length along the mid-longitudinal axis of the implant "that is greater than said first distance and said second distance." Gilles and Albert both teach implants where the first distance as defined in claim 102 is greater than the

second and third distances as defined in claim 102. Neither Gilles nor Albert teach or suggest an implant as claimed in independent claim 102. Applicant submits independent claim 102 is allowable and that dependent claims 103-140 are allowable at least because they depend directly or indirectly from an allowable independent claim, which is submitted to be allowable over the art of record.

Applicant submits that independent claims 1 and 102 are patentable and that dependent claims 3, 5, 6, 8-10, 14, 15, 18-35, 38, 40-42, 101, and 103-140 dependent from one of independent claims 1 and 102, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

Applicant submits that the rejections of claims 1, 3, 5, 6, 8-10, 14, 15, 18-35, 38, 40-42 over the art of record have been overcome.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

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Dated: September 11, 2002

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CHANGES TO THE CLAIMS

Please amend the claim 1 as follows:

1. (Twice amended) An artificial interbody spinal implant for insertion at least in part across the height of a disc space between adjacent vertebral bodies of a human spine, the vertebral bodies having an anterior aspect and a posterior aspect, said implant comprising:

a leading end for insertion first into the disc space, a trailing end opposite said leading end, and therebetween a length along a mid-longitudinal axis of said implant, said leading end being asymmetrical;

opposed portions between said leading and trailing ends adapted to be placed within the disc space to contact and support the adjacent vertebral bodies, said opposed portions being non-arcuate along at least a portion of the length of said implant, each of said opposed portions having at least one opening therein to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant, said implant being formed at least in part of a material other than bone, said material comprising at least one of surgical quality titanium and its alloys, cobalt chrome alloy, tantalum, any metal or alloy suitable for the intended purpose, any ceramic material suitable for the intended purpose, and any plastic or composite material suitable for the intended purpose;

an interior facing side wall, an exterior facing side wall opposite said interior side wall, and a width therebetween, said width of said implant being less

than approximately one-half of the maximum width of the adjacent vertebral bodies into which said implant is adapted to be inserted, said interior and exterior side walls being between said opposed portions and said leading and trailing ends, said interior side wall adapted to be oriented toward another implant when inserted within the disc space, each of said opposed portions having a vertebral body contacting surface between said at least one opening and at least one of said interior side wall and said exterior side wall, each of said vertebral body contacting surfaces being adapted to be placed toward one of the adjacent vertebral bodies, said vertebral body contacting surfaces being spaced apart to define a hollow interior in communication with said openings;

a first distance as measured along the mid-longitudinal axis from said leading end to a plane perpendicular to and bisecting the length along the mid-longitudinal axis of said implant that is greater than a second distance as measured from said perpendicular plane to the junction of said leading end and said exterior side wall; and

a third distance as measured from the junction of said leading end and said interior side wall to the plane perpendicular to and bisecting the length along the mid-longitudinal axis of said implant that is greater than said second distance.

34. (Amended) The implant of claim 1, wherein said opposed portions have at least twoone openings therein~~, said openings being in communication with one another to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant~~.

CHANGES TO THE SPECIFICATION

Please amend the specification as follows:

Page 20, paragraph 2:

--Further, the implant of the present invention preferably includes non-arcuate opposed surface portions that are either generally parallel to one another along the length of the implant or in angular relationship to each other such that the opposed surfaces are closer to each other proximate one end of the implant than at the longitudinally opposite other. For example, at least a portion of the opposed surfaces may be in a diverging relationship to each other from the trailing end to the leading end for allowing angulation of the adjacent vertebral bodies relative to each other. Alternatively, at least a portion of the opposed surfaces may be generally in a converging relationship to each other from the trailing end to the leading end for allowing angulation of the adjacent vertebral bodies relative to each other. The spinal implant of the present invention allows for a variable surface, or any other configuration and relationship of the opposed surfaces.--

Page 17, after line 6, insert the following paragraph:

--In another preferred embodiment, the opposed portions of the implant can be in moveable relationship to each other to allow for relative motion of the adjacent vertebral bodies after the implant is installed.--